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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,920	01/30/2002	Tadashi Ookawa	396.41133X00	4634

20457 7590 05/16/2003

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EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

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DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/058,920

Applicant(s)
Ookawa

Examiner
Leigh Maier

Art Unit
1623



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152) ,
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Status of the Claims

Claims 1-19 are pending and under examination.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims, 1 and 11 recite a process requiring "... pretreating a polysaccharide to enhance water solubility ..." apparently indicating that the process requires the use of polysaccharides that are not water soluble or those having limited water solubility. However, dependent claims recite the use of water soluble polysaccharides, such as pectin and chondroitin. Therefore, it is not clear if this step is required only when an insoluble polysaccharide is used or if some sort of processing is required to make soluble substrates even *more* soluble. The claims are rendered vague and indefinite.

Further regarding claim 8, the claim recites the use of protopectin (and derivatives). The instant specification describes the invention as a process for selectively oxidizing primary

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hydroxyl groups. However, the pectins are polymers of galacturonic acid. This polysaccharide has no unoxidized hydroxyls.

Further regarding claims 9 and 10, the claims recite the term "high" in claims 9 and 10 is a relative term which renders the claims indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Further regarding claim 15, the claim depends from claim 1, but claim 1 does not provide antecedent basis for the limitation "the pretreated polyglycosamine."

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7, and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by BRAGD et al (US 2001/0034442).

BRAGD teaches the oxidation of gelatinized starch with TEMPO and hypochlorite at pH 8.5 in the absence of bromide or iodide. See the example on page 1.

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Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1, 2, 5, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by BESEMER et al (WO 95/07303) with inherency supported by MERCK (12th edition, 1996).

BESEMER '303 discloses the oxidation of potato starch using TEMPO, NaBr, (39 mol %) and NaOCl at pH 10.8. See example VII and Table 2. In example I, the reference indicates that the potato starch being used is soluble. Given that native starch is not soluble, this starch, by definition, has been processed in some manner to enhance its solubility.

MERCK teaches that soluble potato starch is prepared by treating the native starch with dilute HCl. See page 8952.

Claims 1-3, 5, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by BESEMER et al (WO 98/27117).

BESEMER '117 teaches the preparation of oxidized starch with high water-absorbing capability comprising the oxidation of gelatinized starch using TEMPO, NaBr, and NaOCl at pH 10. See examples 6 and 7. The reference is silent regarding the molecular weight of the oxidized products. However, the polysaccharide is treated in the manner required in the claim and has the required physical characteristics. Since the Office does not have the facilities for preparing the

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claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claims 1, 2, 5, 8, 11, 12, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by MUZZARELLI et al (S.T.P. Pharma Sci., 2000).

MUZZARELLI discloses oxidation of chitin using TEMPO, NaBr, and NaOCl at pH 10.8. The chitin is swollen, and this step is deemed indispensable. One of ordinary skill would recognize this process to be equivalent to gelatinization, used to enhance the water solubility of starch. See section 2.1 and Table 1.

Claims 1, 2, 5, 8-12, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by CHANG et al (J. Carbohydr. Chem., 1996).

CHANG discloses the selective oxidation of the primary alcohol moiety of several polysaccharides using TEMPO, NaBr, and NaOCl at pH 10.8. See Table 1 and page 828, last paragraph. Two of the exemplified polysaccharides are chitosan and carboxymethylcellulose (CMC). These are not natural products, and by definition, are deacetylated chitin and etherified cellulose, respectively. These modification processes enhance the solubility of chitin and cellulose. The oxidized products have utility as gums, gels, and films.

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The oxidized CMC forms a gel, indicating high water absorbability but is silent regarding the molecular weight of the oxidized products, including chitosan. See Table 5. However, since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claims 1, 2, 4, 5, and 8-16 are rejected under 35 U.S.C. 102(b) as being anticipated by ISOGAI et al (Cellulose, 1998) with CARDINAL et al (US 4,895,724) to support inherency.

ISOGAI discloses the oxidation of mercerized cellulose, chitin, and chitosan using TEMPO, NaBr, and NaOCl at pH 10. Some of the exemplified celluloses have molecular weight of greater than 200 kD. See Table 1; page 155 - "Oxidation Procedure;" and Table 3.

The reference is silent regarding the water absorbability of the oxidized products. However, the polysaccharides have been oxidized as required in the claims and would have the same physical characteristics. The reference is silent regarding deacetylating chitin to enhance water solubility. However, the reference notes that the chitosan is soluble (see Table 1) and it is known that water solubility of chitin is increased by deacetylation. (See discussion of CARDINAL, below).

Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or

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unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by SZU et al (US 5,738,855).

SZU discloses an O-acetylated pectin having molecular weight of about 400 kD. See example 4. The reference is silent about the precursor non-acetylated pectin. However, a pectin used to prepare the O-acetylated pectin of this molecular weight would have to have a molecular weight of 200 kD or more. The reference further discloses that the pectin precursor forms a gel, evidence of high water absorbability.

The claims recite a product-by-process. However, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by DELLA VALLE et al (US 5,925,626).

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Hyaluronic acid, by Applicant's definition is a polyglycosamine in which more than 40% of what would have been the primary alcohol groups are carboxyl groups. Fractions of various molecular weight are known. See DELLA VALLE abstract, for example.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 12, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over BRAGD et al (US 2001/0034442) as applied to claims 1-3, 5, 7, and 8 in view of MUZZARELLI et al (S.T.P. Pharma Sci., 2000).

The claims are drawn to a method of producing an oxidized polysaccharide by enhancing water solubility of said polysaccharide and oxidizing in the presence of hypochlorous acid or salt thereof and a nitroxyl compound. Dependents recite products and limitations of the method, such as pH and the absence of a bromide or iodide ion, and specific polysaccharide substrates.

BRAGD teaches as set forth above. The reference does not exemplify the oxidation of polyglycosamines. However, the reference specifically suggests the use of polyglycosamines, such as chitin. See page 1, paragraph [0009].

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MUZZARELLI teaches as set forth above.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to oxidize a polyglycosamine, such as chitin, by the process of BRAGD because this substrate is specifically suggested by the reference. It would be further obvious to pretreat the chitin, as taught by MUZZARELLI, in order to facilitate the oxidation. The artisan would reasonably expect success in oxidizing chitin by this method.

Claims 1, 2, 5, 6, and 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over BESEMER et al (WO 95/07303) and ISOGAI et al (Cellulose, 1998).

The claims are drawn to a method of producing an oxidized polysaccharide by enhancing water solubility of said polysaccharide and oxidizing in the presence of hypochlorous acid or salt thereof and a nitroxyl compound. Dependents recite products and limitations of the method, such as pH and inclusion of a bromide or iodide ion, and specific polysaccharide substrates.

BESEMER '303 teaches as set forth above. The reference further suggests the use of this process for the oxidation of any polysaccharide, including polyglycosamines, including chitin. See page 5, first full paragraph. The oxidized polysaccharides produced by this process have utility as gelling agents, thickeners, etc. See page 1, second paragraph.

ISOGAI teaches as set forth above. The reference further teaches that the degree of polymerization (molecular weight) of the oxidation product is dependent on the amount of bromide used in the reaction.

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The references do not specifically exemplify the oxidation of a polyglycosamine with an amount of less than 40 mol% of bromide or iodide.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the process of BESEMER '303 comprising 39 mol% of NaBr to oxidize a polyglycosamine, such as chitin or chitosan for the art disclosed utility with a reasonable expectation of success. It would be within the scope of the artisan to optimize the amount of reagents to produce a desired product through routine experimentation.

Claim 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over MUZZARELLI et al (S.T.P. Pharma Sci., 2000) as applied to claims 1, 2, 5, 8, 11, 12, 15, and 16 in view of CARDINAL et al (US 4,895,724).

The invention is as set forth above. Claims 13 and 14 require pretreatment of the polyglycosamine by controlling the degree of acetylation to 0.3 or higher.

MUZZARELLI teaches as set forth above. The reference is silent regarding enhancing water solubility by controlling the degree of acetylation of the chitin.

CARDINAL teaches that deacetylation of chitin increases its solubility with solubilization beginning about 60% (degree of acetylation of 0.4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process of MUZZARELLI by first deacetylating the chitin. One of ordinary skill would be motivated to do this to enhance the solubility of the chitin to

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facilitate the oxidation process. It would be within the scope of the artisan to optimize the degree of acetylation with routine experimentation.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over CHANG et al (J. Carbohyd. Chem., 1996) as applied to claims 1, 2, 5, 8-12, 15, and 16 in view of MUZZARELLI et al (S.T.P. Pharma Sci., 2000).

The invention is as set forth above.

CHANG teaches as set forth above. As noted above, the molecular weight of the final product cannot be determined from the reference.

MUZZARELLI teaches that several commercially available chitosans having molecular weight of greater than 100 kD. See Table 1.

If it were determined that the CHANG chitosan did not have molecular weight of greater than 100 kD, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select any commercial chitosan to prepare oxidized chitosan for the art disclosed utility. The artisan would reasonably expect that the thus prepared oxidized chitosan would have the physical characteristics recited in the claim.

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Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Monday-Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier
Patent Examiner
May 14, 2003